K003364-A1

# Exhibit 19 Summary of Safety & Effectiveness

JUL 1 8 2001

25 June 2001

The ***Vivo 200 DPS VivoScan*** [tm] Audiometer is designed for clinical applications to allow health care providers to measure, record, display, and store hearing screening tests to discover hearing difficulties. As such, *this device* is a Class II device, having Regulation Number: ***21 CFR part 874.1050,*** ***Classification*** Number: ***77- EWO.***

This summary is submitted in behalf of:
***Vivosonic Inc.***
56 Aberfoyle Crescent, Suite 820,
Toronto, Ontario, Canada M8X 2W4
Voice phone number (416) 231 9997
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This summary is submitted by:
Richard Keen
***Compliance Consultants***
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This device can be **described** as a Class II diagnostic system that sends a series of tones to the ear (cochlea) and measures the reaction of the cochlea (ear) using proprietary techniques and computational processes. This device is composed of:

- Software (that runs on a qualified, ancillary computer),
- A library of DPOAE test protocols,
- Proprietary hardware and software, and a
- Calibrated acoustic probe (which sends and receives the acoustic tones).

All ancillary equipment, which works with this device, is identified as a configured item and tested to formal procedures. This device will only be used with specific ancillary equipment, which is tested and qualified to work with ***Vivo 200 DPS VivoScan*** [tm].

The **scientific concept** on which this device is based is the principle that, by stimulating the cochlea with controlled acoustic tones and then detecting and measuring the reaction of the cochlea to these tones, the patient's hearing abilities can be determined.

This device **functions** by sending/receiving low-level acoustic signals to/from the human ear and interpreting these reactions to compute hearing abilities.

The **intended use** of this device is for a trained health care professional to discover the hearing ability of patients who cannot participate or assist in the conduct of the test (such as infant or geriatric patients). The ***Vivo 200 DPS VivoScan*** [tm] uses sophisticated digital signal processing and data collection/display techniques to offer the physician or trained health care provider, a reliable, simple tool. As advanced as this tool is, this tool is not intended to replace all other testing systems. This device is strictly *a front line tool.*

The ***Vivo 200 DPS VivoScan*** [tm] is indicated for use when it is necessary for a trained health care professional (for example an Audiologist) to measure or determine cochlear function by measuring, recording, and displaying Distortion Product Otoacoustic Emission (DPOAE).

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The ***Vivo 200 DPS VivoScan*** [tm] is indicated for use for patients of all ages from newborn through geriatric patients. The Distortion Product Otoacoustic Emission (DPOAE) test is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults.

This is a prescription device. The labeling, instructions, and user operations are designed for health care professionals. Should the hearing test reveal a hearing difficulty, the device signals the operator to refer the patient to a physician.

***Vivosonic Inc.*** has determined that the ***Vivo 200 DPS VivoScan*** [tm] is substantially equivalent to the performance of a an existing medical device: ***Scout*** [tm] ***Sport Notebook*** manufactured by *Bio-logic Systems* Corp. of Mundelein, IL (K974076). The differences between these systems are incidental and not significant. Both devices use similar technology and principles.

***Vivosonic Inc.*** has determined that *this device* is substantially equivalent to the predicate device and has these similar technological characteristics:

both devices use computers and software having analog/digital control of tones,
both devices generate acoustic tones and receive acoustic tones from the ear,
both use computer algorithm to process, compute and diagnose hearing,
both use a computer algorithm to compute complex signals.

This device is different from the predicate device in that it uses a proprietary DSP algorithm in lieu of conventional Fast Fourier Transform (which work in succession approximations) to acquire, record, and interpret patient data.

A series of factory calibration tests are conducted to verify that the device is accurate, calibrated, and can maintain calibration over its useful life. The ***Vivo 200 DPS VivoScan*** [tm] has benefited from design, development, testing, and production procedures that conform to Quality Systems.

*This device* is safe and effective for the application for which it is intended, and has been tested to confirm safety and efficacy. ***Vivosonic Inc.*** continues to search all appropriate sources for information relating to safety and effectiveness, and maintains an *in-house* reporting system to identify adverse safety and effectiveness information, and as such, applicable data are recorded for this product.

**CERTIFICATION:**
I hereby certify this **Summary of Safety and Effectiveness** applies for the above-indicated device.

Dr. Yuri Sokolov
President and Chief Executive Officer
***Vivosonic Inc.***
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vivsonic, Inc.
c/o Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K003364
Trade Name: Vivo 200 DPS Vivoscan™
Regulatory Class: II
Regulation: CFR 874.1050
Product Code: 77EWO
Dated: May 22, 2001
Received: May 23, 2001

Dear Mr. Keen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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K003364

**Exhibit 2**

**510(K) Number (If known): _____no 510(K) number assigned__**

**Device Name: __ *Vivo 200 DPS Vivoscan* ™ Hearing Screening System, *Model DPS 200***

## Indications for Use

The ***Vivo 200 DPS Vivoscan*** ™ is indicated for use when it is necessary for a trained health care professional (for example an Audiologist) to measure or determine cochlea function by measuring, recording and displaying distortion product otoacoustic emissions. This device is a hearing screening device that does not measure hearing, but helps to determine whether or not a hearing loss may be present, requiring further evaluation.

The ***Vivo 200 DPS Vivoscan*** ™ does not measure hearing per se, but measures whether or not the cochlear hair cells are functioning. This device does not determine hearing levels, but allows the operator to establish specific pass or fail criteria.

The ***Vivo 200 DPS Vivoscan*** ™ is indicated for use for patients of all ages from newborn through adults, to and including geriatric patients. The distortion product otoacoustic emissions test is especially indicated for use in testing individuals for whom behavior acousticmetric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults.

This Audiometer is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**(Division Sign-Off)**
**Division of Ophthalmic Devices**
**510(k) Number** K003364

**Prescription Use** X
**(Per 21 CFR 801.109)**

**or Over - The - Counter Use** ___ _____

**(Optional Format 1-2-96)**